APPENDIX A

The Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040 [21 U.S.C.A. (Supp.) 301, *et seq.*], in parts pertinent to this case, provides:

"Sec. 401 (21 U.S.C.A. 341). *Whenever* in the judgment of the Administrator *such action will promote honesty and fair dealing in the interest of consumers*, he shall promulgate regulations fixing and establishing for any food, *under its common or usual name so far as practicable*, a *reasonable* definition and standard of identity, a *reasonable* standard of quality, *and/or reasonable* standards of fill of container * * *.

"Sec. 701(a) [21 U.S.C.A. 371(a)]. The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Administrator.

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"Sec. 701(c) [21 U.S.C.A. 371(c)]. Hearings authorized or required by this Act shall be conducted by the Administrator or such officer or employee as he may designate for the purpose.

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"Sec. 701(e) [21 U.S.C.A. 371(e)]. The Administrator, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, *shall hold a public hearing* upon a *proposal* to issue, amend, or repeal any regulation contemplated by any of the following sections of this Act: 401 * * * The Administrator shall give *appropriate* notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon *not less than thirty*

days after the date of the notice, * * *. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Administrator shall by order make public his action in issuing, amending or repealing the regulation or determining not to take such action. The Administrator shall base his order *only on substantial evidence of record at the hearing* and shall set forth as part of the order detailed findings of fact on which the order is based. * * *

"Sec. 701(f) [21 U.S.C.A. 371(f)]. In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may * * * file a petition with the Circuit Court of Appeals of the United States * * *. The Administrator, promptly upon service of the summons and petition, shall certify and file in the court the transcript of the proceedings and the record on which the Administrator based his order.

"(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Administrator, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Administrator, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Administrator may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his

recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

"(3) The court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If * * * such order is *not in accordance with law* the court shall by its judgment order the Administrator to take action * * * in accordance with law. *The findings of* the Administrator as to the *facts, if supported by substantial evidence, shall be conclusive.*

"(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Administrator shall be final, subject to review by the Supreme Court of the United States upon *certiorari* or *certification* as provided in sections 239 and 240 of the Judicial Code, as amended.

"(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Administrator or any vacancy in such office.

"(6) The remedies provided * * * shall be in addition to * * * any other remedies provided by law."

The Administrative Procedure Act of June 11, 1946, c. 324, 60 Stat. 237 [5 U.S.C.A. (Supp.) 1001, *et seq.*], in parts pertinent to this case provides:

"DEFINITIONS

"Sec. 2 (5 U.S.C.A. 1001) as used in this Act—

"(a) AGENCY.—'Agency' means each authority * * * of the Government of the United States. * * * * * * * *

"(c) RULE AND RULE MAKING.—'Rule' means the whole or any part of any agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy * * * and includes the approval or prescription for the future of rates * * * or practices * * *. 'Rule making' means agency process for the formulation, amendment, or repeal of a rule.

"(d) ORDER AND ADJUDICATION.—'Order' means the whole or any part of the final disposition (whether affirmative, negative, injunctive, or declaratory in form) of any agency in any matter other than rule making but including licensing. 'Adjudication' means agency process for the formulation of an order.

"(e) LICENSE AND LICENSING.—'License' includes the whole or part of any agency *permit*, certificate, *approval*, registration, charter, membership, statutory exemption or other form of permission. 'Licensing' includes agency process respecting the grant, renewal, denial, revocation, suspension, annulment, withdrawal, limitation amendment, modification, or conditioning of a license.

* * * * * * *

"(g) AGENCY PROCEEDING AND ACTION.—'Agency proceeding' means any agency process as defined in subsections (c), (d), and (e) of this section. 'Agency action' includes the whole or part of every agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act.

"PUBLIC INFORMATION

"Sec. 3. (5 U.S.C.A. 1002) * * *

"(a) RULES.—*Every agency shall separately state and currently publish in the Federal Register* * * * (3) *substantive rules adopted as authorized by law and statements of general policy or interpretations formulated and adopted by the agency for the guidance of the public, but not rules addressed to and served upon named persons in accordance with law. No person shall in any manner be required to resort to organization or procedure not so published.*

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"RULE MAKING

"Sec. 4 (5 U.S.C.A. 1003) * * *

"(a) NOTICE.—General notice of proposed rule making shall be published in the Federal Register * * * and shall include (1) a statement of the time, place, and nature of public rule making proceedings; (2) reference to the authority under which the rule is proposed; and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved. Except where notice or hearing is required by statute, this subsection shall not apply to interpretative rules, general statements of policy, rules of agency organization, procedure, or practice, * * *.

* * * * * * *

"(b) PROCEDURES.—* * *. *Where rules are required by statute to be made on the record after opportunity for an agency hearing, the requirements of sections 7 and 8 shall apply* in place of the provisions of this subsection.

"ADJUDICATION

"Sec. 5 (5 U.S.C.A. 1004). *In every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing,* * * *.

"(a) NOTICE.—*Persons entitled to notice of an agency hearing shall be timely informed of* (1) the time, place, and nature thereof; (2) the legal authority and jurisdiction under which the hearing is to be held; and (3) *the matters of fact and law asserted. In instances in which private persons are the moving parties, other parties to the proceeding shall give prompt notice of issues controverted in fact or law; and in other instances agencies may by rule require responsive pleading. In fixing the times and places for hearings, due regard shall be had for the convenience and necessity of the parties or their representatives.*

* * * * * * * *

"(c) SEPARATION OF FUNCTIONS.—The same officers who preside at the reception of evidence pursuant to section 7 shall make the recommended decision or initial decision required by section 8 except where such officers become unavailable to the agency. * * *, no such officer shall consult any person or party on any fact in issue unless upon notice and opportunity for all parties to participate; nor shall such officer be responsible to or subject to the supervision or direction of any officer, employee, or agent engaged in the performance of investigative or prosecuting functions for any agency. *No officer, employee, or agent engaged in the performance of investigative or prosecuting functions* for any agency in any case *shall*, in that or a factually related case, *participate or advise in the decision*, recommended decision, or agency review pursuant to section 8

except as witness or counsel in public proceedings. This subsection shall not apply in determining applications for initial licenses or to proceedings involving * * * rates, facilities, or practices of public utilities or carriers; nor shall it be applicable in any manner to the agency or any member or members of the body comprising the agency. * * *

"HEARINGS

"Sec. 7. (5 U.S.C.A. 1006). *In hearings* which section 4 or 5 requires to be conducted pursuant to this section—

"(a) PRESIDING OFFICERS.—There shall preside at the taking of evidence (1) the agency, (2) one or more members of the body which comprises the agency, or (3) one or more examiners appointed as provided in this Act; * * *. The functions of all presiding officers and of officers participating in decisions in conformity with section 8 shall be conducted in an impartial manner. * * *

"(b) HEARING POWERS.—*Officers presiding at hearings shall have authority,* subject to the published rules of the agency and within its powers, *to* (1) administer oaths and affirmations, (2) issue subpoenas authorized by law, (3) *rule upon offers of proof and receive relevant evidence,* (4) take or cause depositions to be taken whenever the ends of justice would be served thereby, (5) regulate the course of the hearing, (6) hold conferences for the settlement or simplification of the issues by consent of the parties, (7) dispose of procedural requests or similar matters, (*8*) *make decisions or recommend decisions in conformity with section 8, and (9) take any other action authorized by agency rule consistent with this Act.*

"(c) EVIDENCE.—Except as statutes otherwise provide, *the proponent of a rule or order shall have the burden of proof.* Any oral or documentary evidence may be received, but *every agency shall* as a matter of policy *provide for* the *exclusion of irrelevant,* * * * *evidence and no* sanction shall be imposed or *rule or order be issued except upon consideration of the whole record* * * * *and as supported by* and in accordance with the *reliable, probative, and substantial evidence.* Every party shall have the right to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. * * *

"(d) RECORD.—The transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, shall constitute the exclusive record for decision in accordance with section 8 * * *. *Where any agency decision rests on official notice of a material fact not appearing in the evidence in the record, any party shall* on timely request *be afforded an opportunity to show the contrary.*

"DECISIONS

"Sec. 8. (5 U.S.C.A. 1007). In cases in which a hearing is required to be conducted in conformity with section 7—

"(a) ACTION BY SUBORDINATES.—In cases in which the agency has not presided at the reception of the evidence, the officer who presided (or, in cases not subject to subsection (c) of section 5, any other officer or officers qualified to preside at hearings pursuant to section 7) shall initially decide the case or the agency shall require (in specific cases or by general rule) the entire record

to be certified to it for initial decision. Whenever such officers make the initial decision and in the absence of either an appeal to the agency or review upon motion of the agency within time provided by rule, such decision shall without further proceedings then become the decision of the agency. On appeal from or review of the initial decisions of such officers the agency shall, except as it may limit the issues upon notice or by rule, have all the powers which it would have in making the initial decision. Whenever the agency makes the initial decision without having presided at the reception of the evidence, such officers shall first recommend a decision except that in rule making or determining applications for initial licenses (1) in lieu thereof the agency may issue a tentative decision or any of its responsible officers may recommend a decision or (2) any such procedure may be omitted in any case in which the agency finds upon the record that due and timely execution of its functions imperatively and unavoidably so requires.

"(b) SUBMITTALS AND DECISIONS.—Prior to each recommended, initial, or tentative decision, or decision upon agency review of the decision of subordinate officers the parties shall be afforded a reasonable opportunity to submit for the consideration of the officers participating in such decisions (1) proposed findings and conclusions, or (2) exceptions to the decisions or recommended decisions of subordinate officers or to tentative agency decisions, and (3) supporting reasons for such exceptions or proposed findings or conclusions. The record shall show the ruling upon each such finding, conclusion, or exception presented. All decisions (including initial, recommended, or tentative decisions)

shall become a part of the record and include a statement of (1) findings and conclusions, as well as the reasons or basis therefor, upon all the material issues of fact, law, or discretion presented on the record; and (2) the appropriate rule, order, sanction, relief, or denial thereof.

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"JUDICIAL REVIEW

"Sec. 10. (5 U.S.C.A. 1009) * * *

"(a) RIGHT OF REVIEW.—Any person suffering legal wrong because of any agency action, or adversely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof.

* * * * * * * * *

"(c) REVIEWABLE ACTS.—*Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action.* * * *

* * * * * * * *

"(e) SCOPE OF REVIEW.—*So far as necessary to decision* and where presented *the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of any agency action. It shall* * * * (B) *hold unlawful and set aside* agency action, *findings, and conclusions found to be* (1) *arbitrary, capricious, an abuse of discretion,* or otherwise not in accordance with law; (2) *contrary to*

constitutional right, power, privilege, or immunity; (3) *in excess of statutory jurisdiction*, authority, or limitations, or short of statutory right; (4) *without observance of procedure required by law;* (5) *unsupported by substantial evidence* in any case subject to the requirements of sections 7 and 8 or otherwise reviewed on the record of an agency hearing provided by statute; * * * *In making the foregoing determinations the court shall review the whole record or such portions thereof as may be cited by any party*, and due account shall be taken of the rule of prejudicial error."

* * * * * * * *

"CONSTRUCTION AND EFFECT

"Sec. 12. *Nothing in this Act shall be held to diminish the constitutional rights of any person or to limit or repeal additional requirements imposed by statute or otherwise recognized by law. Except as otherwise required by law, all requirements or privileges relating to evidence or procedure shall apply equally to agencies and persons.* * * *"